HAB HIV Core Clinical Performance Measures for Adult/Adolescent Clients: Group 1

<table>
<tr><td colspan="2">Performance Measure: CD4 T-cell count</td><td>OPR Measure: #2</td></tr>
<tr><td colspan="3">Percentage of clients with HIV infection who had 2 or more CD4 T-cell counts performed in the measurement year</td></tr>
<tr><td>Numerator:</td><td colspan="2">Number of HIV-infected clients who had 2 or more CD4 T-cell counts performed at least 3 months apart during the measurement year</td></tr>
<tr><td>Denominator:</td><td colspan="2">Number of HIV-infected clients who had a medical visit with a provider with prescribing privileges[1], i.e. MD, PA, NP at least once in the measurement year</td></tr>
<tr><td>Patient Exclusions:</td><td colspan="2">1. Patients newly enrolled in care during last six months of the year</td></tr>
<tr><td>Data Element:</td><td colspan="2">2. Is the client HIV-infected? (Y/N)
3. If yes, did the client have a CD4 count test conducted during the reporting period? (Y/N)
a. If yes, list the quarters of these tests</td></tr>
<tr><td>Data Sources:</td><td colspan="2">• Electronic Medical Record/Electronic Health Record
• CAREWare, Lab Tracker, or other electronic data base
• HIVQUAL reports on this measure for grantee under review
• Medical record data abstraction by grantee of a sample of records</td></tr>
<tr><td>National Goals, Targets, or Benchmarks for Comparison</td><td colspan="2">IHI Goal: 90%[2]
National HIVQUAL Data: [3]
<table>
<tr><td></td><td>2003</td><td>2004</td><td>2005</td><td>2006</td></tr>
<tr><td>Top 10%</td><td>87.2%</td><td>87.7%</td><td>90.3%</td><td>87.5%</td></tr>
<tr><td>Top 25%</td><td>74.2%</td><td>78.0%</td><td>76.6%</td><td>78.8%</td></tr>
<tr><td>Median*</td><td>61.0%</td><td>62.7%</td><td>63.9%</td><td>62.5%</td></tr>
</table>
*from HAB data base</td></tr>
<tr><td>Outcome Measures for Consideration</td><td colspan="2">° Rate of opportunistic infections in the measurement year
° Rate of clients with progression to AIDS in the measurement year
° Mortality rates</td></tr>
<tr><td colspan="3">Basis for Selection and Placement in Group 1:</td></tr>
<tr><td colspan="3">The CD4 T-cell count plays a vital role in determining the staging of HIV disease and indicating the need for prophylaxis against opportunistic infections. It continues to be used in decisions regarding initiation or adjustment of antiretroviral treatment.

The most recent CD4 T-cell count is the strongest predictor of subsequent disease progression and survival, according to clinical trials and cohort studies data on patients receiving antiretroviral therapy.[4]

Measure reflects important aspects of care that significantly impacts survival and mortality. Data collection is currently feasible and measure has a strong evidence base supporting the use.</td></tr>
<tr><td colspan="3">US Public Health Service Guidelines:</td></tr>
</table>

" In general, CD4 T-cell count should be determined every three to six months to (1) determine when to start antiretroviral in patients who do not meet the criteria for initiation; (2) assess immunologic response to antiretroviral therapy; and (3) assess the need for initiating chemoprophylaxis for opportunistic infections." [3]

References/Notes:

Guidelines state that CD4 T-cell counts should be measured at least every 3-4 months depending on the stage of the disease. The timeframe of 6 months was determined by clinical expert consensus for the purpose of this measure, but can and should be measured at more frequent intervals if needed.

[1]A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

[2]IHI Measure reads, "Percent of Patients/Clients with a CD4 Count Test in the Past 4 Months" (http://www.ihi.org/IHI/Topics/HIVAIDS/HIVDiseaseGeneral/Measures/Percentof+patientswithaCD4countestinthepast4months.htm)

[3]National HIVQUAL data looks at the percent of clients who have a CD4 T-cell count done every four months, not every six months. (http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf)

[4]Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services. December 1, 2007; 1-143. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed December 12, 2007.

HAB HIV Core Clinical Performance Measures for Adult/Adolescent Clients: Group 1

U.S. Department of Health and Human Services HRSA Health Resources and Services Administration

<table>
<tr><td colspan="2">Performance Measure: HAART</td><td>OPR Measure: #12a</td></tr>
<tr><td colspan="3">Percentage of clients with AIDS who are prescribed HAART</td></tr>
<tr><td>Numerator:</td><td colspan="2">Number of clients with AIDS who were prescribed a HAART regimen[1] within the measurement year</td></tr>
<tr><td>Denominator:</td><td colspan="2">Number of clients who:
• have a diagnosis of AIDS (history of a CD4 T-cell count below 200 cells/mm^3 or other AIDS-defining condition[2]), and
• had at least one medical visit with a provider with prescribing privileges[3], i.e. MD, PA, NP in the measurement year.</td></tr>
<tr><td>Patient Exclusions:</td><td colspan="2">1. Patients newly enrolled in care during last three months of the measurement year</td></tr>
<tr><td>Data Element:</td><td colspan="2">1. Is the client diagnosed with CDC-defined AIDS? (Y/N)
2. If yes, was the client prescribed HAART during the reporting period? (Y/N)</td></tr>
<tr><td>Data Sources:</td><td colspan="2">• Program Data Report, Section 2, Items 26 and 31 may provide data useful in establishing a baseline for this performance measure
• Electronic Medical Record/Electronic Health Record
• CAREWare, Lab Tracker, or other electronic data base.
• HIVQUAL reports on this measure for grantee under review
• Medical record data abstraction by grantee of a sample of records</td></tr>
<tr><td>National Goals, Targets, or Benchmarks for Comparison</td><td colspan="2">IHI Goal: 90%[4]

CDC and HIVRN data consistent that 80% of those in care “eligible for ARVs” on tx. This includes CD4<350 and not just AIDS.[5,6]

National HIVQUAL Data:[7,8]
<table>
<tr><td></td><td>2003</td><td>2004</td><td>2005</td><td>2006</td></tr>
<tr><td>Top 10%</td><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
<tr><td>Top 25%</td><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
<tr><td>Median*</td><td>100%</td><td>88.9%</td><td>95.7%</td><td>100%</td></tr>
</table>
*from HAB data base</td></tr>
<tr><td>Outcome Measures for Consideration:</td><td colspan="2">° Rate of opportunistic infections in the measurement year
° Rate of HIV-related hospitalizations in the measurement year
° Mortality rates</td></tr>
<tr><td colspan="3">Basis for Selection and Placement in Group 1:</td></tr>
<tr><td colspan="3">**“**Randomized clinical trials provide strong evidence of improved survival and reduced disease progression by treating symptomatic patients and patients with CD4 T-cells <200 cells/mm^3.”[9]

Measure reflects important aspect of care that significantly impacts survival, mortality and hinders transmission. Data collection is currently feasible and measure has a strong evidence base supporting the use.</td></tr>
<tr><td colspan="3">US Public Health Service Guidelines:</td></tr>
</table>

"Antiretroviral therapy is recommended for all patients with history of an AIDS-defining illness or severe symptoms of HIV infection regardless of CD4 T-cell count."[10]

References/Notes:

[1]Many authorities recommend two baseline CD4 T-cell measurements before decisions are made to initiate antiretroviral therapy because of wide variations in results. The test should be repeated yet a third time if discordant results are seen. The optimal time to initiate antiretroviral therapy among asymptomatic patients with CD4 T-cell counts >200 cells/mm^3 is unknown. This measure focuses strictly on the subset of patients for whom antiretroviral therapy is unequivocally recommended—those with a CD4 T-cell count below 200 cells/mm^3 or history of another AIDS-defining condition. Asymptomatic patients with CD4 T-cell counts of 201–350 cells/mm^3 should be offered treatment. For asymptomatic patients with CD4 T-cell of >350 cells/mm^3 and plasma HIV RNA >100,000 copies/ml most experienced clinicians defer therapy but some clinicians may consider initiating treatment. (See reference 8 below)

[2]AIDS Defining conditions are noted in CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(no. RR-17). (http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm)

[3]A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

[4]IHI Measure reads, "Percent of Patients with Appropriate ARV Therapy Management" http://www.ihi.org/IHI/Topics/HIVAIDS/HIVDiseaseGeneral/Measures/PercentofPatientswithAppropriateARVTherapyManagement.htm)

[5] Gebo, JAIDS January 2005, vol. 38, pp. 96-103.

[6] Teshale Abstract #167, CROI 2005.

[7] The National HIVQUAL data may not be directly comparable due to varying exclusions. Indicator definitions can be accessed at http://www.hivguidelines.org/Content.aspx?PageID=53.

[8]http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf

[9]"HAART, CD4<200" (http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf)

[10]Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services. December 1, 2007; p. 9. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed December 12, 2007.

HAB HIV Core Clinical Performance Measures for Adult/Adolescent Clients: Group 1

U.S. Department of Health and Human Services HRSA Health Resources and Services Administration

Performance Measure: Medical Visits	**OPR Measure:** #1
Percentage of clients with HIV infection who had two or more medical visits in an HIV care setting in the measurement year	
Numerator:	Number of HIV-infected clients who had a medical visit with a provider with prescribing privileges[1], i.e. MD, PA, NP, in an HIV care setting[2] two or more times at least 3 months apart during the measurement year
Denominator:	Number of HIV-infected clients who had a medical visit with a provider with prescribing privileges at least once in the measurement year
Patient Exclusions:	1. Patients newly enrolled in care during last six months of the year
Data Element:	1. Is the client HIV-infected? (Y/N) 2. Did the client have medical visits in an HIV care setting during the reporting period? (Y/N) a. If yes, list the quarters of these visits
Data Sources:	• Program Data Report, Section 5, Items 42 and 43 may provide data useful in establishing a baseline for this performance measure • Electronic Medical Record/Electronic Health Record • CAREWare, Lab Tracker, or other electronic data base • HIVQUAL reports on this measure for grantee under review • Medical record data abstraction by grantee of a sample of records
National Goals, Targets, or Benchmarks for Comparison	None available at this time.
Outcome Measures for Consideration	° Rate of HIV-related hospitalizations in the measurement year ° Rate of HIV-related emergency room visits in the measurement year ° Rate of opportunistic infections in the measurement year ° Mortality rates
Basis for Selection and Placement in Group 1:	
Clinicians should schedule routine monitoring visits at least every 4 months for all HIV-infected patients who are clinically stable.[3,4] Greater experience among primary care physicians in the care of persons with AIDS improves survival.[5] Measure reflects important aspects of care that significantly impacts mortality. Data collection is currently feasible and measure has a strong evidence base supporting the use.	
US Public Health Service Guidelines:	
In general, patients with early-stage disease are seen at 3-month intervals to undergo routine medical evaluation and monitoring of CD4 T-cell count, viral load and CBC. During the initial evaluation more frequent visits are common because there is so much information to transmit. Visits should also be more frequent when therapy is introduced and when the CD4 T-cell count is <200 cells/mm^3 because complications are more likely.[6]	

Multiple studies have demonstrated that better outcomes are achieved in patients cared for by a clinician with expertise. This has been shown in terms of mortality, rate of hospitalizations, compliance with guidelines, cost of care, and adherence to medications. The definition of expertise in these studies has varied, but most rely on the number of patients actively managed. Based on this observation, the Panel recommends HIV primary care by a clinician with at least 20 HIV-infected patients and preferably at least 50 HIV-infected patients. Many authoritative groups have combined the recommendation based on active patients, along with fulfilling ongoing CME requirements on HIV-related topics. [7]

References/Notes:

Guidelines state that routine monitoring of HIV-infected patients should occur at least every 3-4 months depending on the stage of the disease. [7] The timeframe of 6 months was determined by clinical expert consensus for the purpose of this measure, but CD4 T-cell counts can and should be measured at more frequent intervals if needed.

[1]A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

[2]An HIV care setting is one which received Ryan White HIV/AIDS Treatment Modernization Act of 2006 funding to provide HIV care and has a quality management program in place to monitor the quality of care addressing gaps in quality of HIV care.

[3]New York State Department of Health. Primary care approach to the HIV-infected patient. New York: New York State Department of Health; 2004. p. 8. http://www.hivguideliens.org/Content.aspx?pageID=257[Accessed November 27, 2007].

[4]AETC National Resource Center. Clinical Manual for Management of the HIV-Infected Adult http://www.aidsetc.org/pdf/AETC-CM_071007.pdf [Accessed November 27, 2007].

[5]Kitahata MM, Van Rompaey SE, Dillingham PW, Koepsell TD, Deyo RA, Dodge W, Wagner EH. Primary care delivery is associated with greater physician experience and improved survival among persons with AIDS. J Gen Intern Med. 2003 Feb;18(2):157-8.

[6]Bartlett JG, Cheever LW, Johnson MP, Paauw DS [eds]. A Guide to Primary Care of People with HIV/AIDS. Rockville(MD): US Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau; 2004, p. 167. http://hab.hrsa.gov/tools/primarycareguide/. [Accessed November 27, 2007].

[7]Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services. December 1, 2007; 1-143. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed December 12, 2007.

HAB HIV Core Clinical Performance Measures for Adult/Adolescent Clients: Group 1

U.S. Department of Health and Human Services HRSA Health Resources and Services Administration

<table>
<tr><td colspan="2">Performance Measure: PCP Prophylaxis</td><td>OPR Measure: #3</td></tr>
<tr><td colspan="3">Percentage of clients with HIV infection and a CD4 T-cell count below 200 cells/mm^3 who were prescribed PCP prophylaxis</td></tr>
<tr><td>Numerator:</td><td colspan="2">Number of HIV-infected clients with CD4 T-cell counts below 200 cells/mm^3 who were prescribed PCP prophylaxis</td></tr>
<tr><td>Denominator:</td><td colspan="2">Number of HIV-infected clients who:
• had a medical visit with a provider with prescribing privileges[1], i.e. MD, PA, NP at least once in the measurement year, and
• had a CD4 T-cell count below 200 cells/mm^3</td></tr>
<tr><td>Patient Exclusions:</td><td colspan="2">1. Patients with CD4 T-cell counts below 200 cells/mm^3 repeated within 3 months rose above 200 cells/mm^3
2. Patients newly enrolled in care during last three months of the measurement year</td></tr>
<tr><td>Data Element:</td><td colspan="2">1. Is the client HIV-infected? (Y/N)
2. If yes, was the CD4 T-cell count <200 cells/mm^3? (Y/N)
3. If yes, was PCP prophylaxis prescribed? (Y/N)
a. If no, was the CD4 count repeated within 3 months? (Y/N)
b. If yes, did it remain below 200 cells/mm^3? (Y/N)
i. If yes, was PCP prophylaxis prescribed? (Y/N)</td></tr>
<tr><td>Data Sources:</td><td colspan="2">• Electronic Medical Record/Electronic Health Record
• CAREWare, Lab Tracker, or other electronic data base
• HIVQUAL reports on this measure for grantee under review
• Medical record data abstraction by grantee of a sample of records</td></tr>
<tr><td>National Goals, Targets, or Benchmarks for Comparison:</td><td colspan="2">IHI Goal: 95%[2]
National HIVQUAL Data[3]:
<table>
<tr><td></td><td>2003</td><td>2004</td><td>2005</td><td>2006</td></tr>
<tr><td>Top 10%</td><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
<tr><td>Top 25%</td><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
<tr><td>Median*</td><td>93.3%</td><td>90.9%</td><td>92.3%</td><td>94.4%</td></tr>
</table>
*from HAB data base</td></tr>
<tr><td>Outcome Measures for Consideration:</td><td colspan="2">° Rate of PCP in the measurement year
° Mortality rates
° Cost savings</td></tr>
<tr><td colspan="3">Basis for Selection and Placement in Group 1:</td></tr>
<tr><td colspan="3">Pneumocystis pneumonia (PCP) is the most common opportunistic infection in people with HIV. Without treatment, over 85% of people with HIV would eventually develop PCP. It is a major cause of mortality among persons with HIV infection, yet is almost entirely preventable and treatable. Pneumocystis almost always affects the lungs, causing a form of pneumonia. People with CD4 T-cell counts under 200 cells/mm^3 are at greatest risk of developing PCP. The drugs now used to prevent and treat PCP include TMP/SMX,</td></tr>
</table>

dapsone, pentamidine, and atovaquone.[4]

Before the widespread use of primary PCP prophylaxis and effective ART, PCP occurred in 70%--80% of patients with AIDS. The course of treated PCP was associated with a mortality rate of between 20% and 40% in persons with profound immunosuppression. Approximately 90% of cases occurred among patients with CD4 T-cell counts <200 cells/mm^3. [5]

Measure reflects important aspect of care that significantly impacts survival and mortality. Data collection is currently feasible and measure has a strong evidence base supporting the use.

US Public Health Service Guidelines:

HIV-infected adults and adolescents, including pregnant women and those on HAART, should receive chemoprophylaxis against PCP if they have a CD4 T-cell count <200 cells/mm^3.[6]

References/Notes:

[1]A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

[2] IHI Measure reads, "Percent of Patients with a CD4 Cell Count Below 200 cells/mm^3 Receiving Pneumocystis Carinii Pneumonia (PCP) Prophylaxis"

[3](http://www.hivguidelines.org/admin/files/qoc/hivqual/proj%20info/HQNatlAggScrs3Yrs.pdf)

[4] http://www.aidsinfonet.org/factsheet_detail.php?fsnumber=515

[5] Centers for Disease Control and Prevention. Treating opportunistic infections among HIV-infected adults and adolescents: recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association/Infectious Diseases Society of America. MMWR 2004;53(No. RR-15) (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5315a1.htm)

[6] Centers for Disease Control and Prevention. Guidelines for Preventing Opportunistic Infections Among HIV-Infected Persons — 2002 Recommendations of the U.S. Public Health Service and the Infectious Diseases Society of America. MMWR 2002;51 (No. RR-8) (http://www.cdc.gov/mmwr/PDF/rr/rr5108.pdf or http://aidsinfo.nih.gov/ContentFiles/OIpreventionGL.pdf)

Performance Measure: ARV Therapy for Pregnant Women	**OPR Measure:** #17
Percentage of pregnant women with HIV infection who are prescribed antiretroviral therapy	
Numerator:	Number of HIV-infected pregnant women who were prescribed antiretroviral therapy during the 2nd and 3rd trimester
Denominator:	Number of HIV-infected pregnant women who had a medical visit with a provider with prescribing privileges[1], i.e. MD, PA, NP at least once in the measurement year
Patient Exclusions:	1. Patients whose pregnancy is terminated 2. Pregnant patients who are in the 1st trimester and newly enrolled in care during last three months of the measurement year
Data Element:	1. Is the client HIV-infected? (Y/N) 2. If yes, is the client female? (Y/N) 3. If yes, was she pregnant during the reporting period? (Y/N) a. If yes, was she on antiretroviral therapy during this reporting period? (Y/N)
Data Sources:	• Program Data Report, Section 5, Item 53 may provide data useful in establishing a baseline for this performance measure • Electronic Medical Record/Electronic Health Record • CAREWare, Lab Tracker, or other electronic data base • Medical record data abstraction by grantee of a sample of records
National Goals, Targets, or Benchmarks for Comparison:	None available at this time.
Outcome Measures for Consideration:	° Rate of perinatal transmission in the measurement year ° Number of events of perinatal transmission in the measurement year

Basis for Selection and Placement in Group 1:

Treatment recommendations for pregnant women infected with HIV-1 have been based on the belief that therapies of known benefit to women should not be withheld during pregnancy unless there are known adverse effects on the mother, fetus, or infant and unless these adverse effects outweigh the benefit to the woman. Antiretroviral therapy can reduce perinatal HIV-1 transmission by nearly 70%.[2]

Measure reflects important aspect of care that significantly impacts survival, mortality and hinders transmission. Data collection is currently feasible and measure has a strong evidence base supporting the use.

US Public Health Service Guidelines:

Health-care providers considering the use of antiretroviral agents for HIV-1 infected women during pregnancy must take into account two separate but related issues:

- Antiretroviral treatment of maternal HIV-1 infection, and
- Antiretroviral chemoprophylaxis to reduce the risk for perinatal HIV-1 transmission

The benefits of antiretroviral therapy for a pregnant woman must be weighed against the risk of adverse

events to the woman, fetus, and newborn. Although ZDV chemoprophylaxis alone has substantially reduced the risk for perinatal transmission, antiretroviral monotherapy is now considered suboptimal for treatment of HIV-1 infection, and combination drug regimens are considered the standard of care for therapy. Initial evaluation of an infected pregnant woman should include an assessment of HIV-1 disease status and recommendations regarding antiretroviral treatment or alteration of her current antiretroviral regimen.

This assessment should include the following:

- Evaluation of the degree of existing immunodeficiency determined by CD4 T-cell count,
- Risk for disease progression as determined by the level of plasma RNA,
- History of prior or current antiretroviral therapy,
- Gestational age, and
- Supportive care needs.

Decisions regarding initiation of therapy should be the same for women who are not currently receiving antiretroviral therapy and for women who are not pregnant, with the additional consideration of the potential impact of such therapy on the fetus and infant.

Further, use of ZDV alone should not be denied to a woman who wishes to minimize exposure of the fetus to other antiretroviral drugs and therefore, after counseling, chooses to receive only ZDV during pregnancy to reduce the risk for perinatal transmission.[1]

References/Notes:

[1]A "provider with prescribing privileges" is a health care professional who is certified in their jurisdiction to prescribe ARV therapy.

[2]Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States (http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf)